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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,646	12/07/2001	Peter W. Bringmann	BERLX 87	7678

7590 09/08/2005

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/005,646	Applicant(s) BRINGMANN ET AL.	
	Examiner Christine J. Saoud	Art Unit 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 and 15 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 14 August 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): written description rejection of claim 40.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 36-41 and 69.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
 13. ☐ Other: _____.

CHRISTINE J. SAOUD
 PRIMARY EXAMINER

Christine J. Saoud

Continuation of 11. does NOT place the application in condition for allowance because: applicant's arguments are not persuasive to overcome the rejection of the claims under 35 USC 103(a). Applicant argues that Webster in view of Nakamura et al. do not motivate one skilled in the art to use FGF-9 for treatment of MS and the references of Webster and Nakamura et al. do not teach or suggest the administration of FGF-9 for the treatment of MS. Applicant argues that the "speculative statements of Webster and/or Nakamura are not enabled and supported by objective evidence in the references for any specific growth factors for the treatment of any specific disease, and more particularly, are not enabled or supported by objective evidence for the use of FGF9 for the treatment of MS".

Applicant's arguments have been fully considered, but are not deemed persuasive. Webster was cited for the teachings that growth factors, including FGFs, are involved in the proliferation, differentiation and survival of cells in the oligodendroglial lineage, and that oligodendroglia are the cells that form and maintain myelin sheaths. Webster teaches that administration of growth factors could increase proliferation of progenitor oligodendrocytes, enhance their differentiation, upregulate synthesis of myelin constituents and promote myelin regeneration in the adult CNS, which would be beneficial for treatment of MS. Therefore, Webster teaches that growth factors which have particular biological activities on the cells that form and maintain myelin sheaths would be beneficial for treatment of MS. Webster does not teach FGF-9 administration for the treatment of MS. Nakamura et al. teach a number of biological activities for FGF-9, including the ability to promote proliferation of primary cortical astrocytes, oligodendrocyte type 2 astrocyte progenitor cells, fibroblasts and neuron-like PC-12 cells. Based on the teaching of Webster that growth factors with particular activities could be used to treat MS, and the teachings of Nakamura et al. that FGF-9 has biological activities consistent with those which would be deemed useful for treatment of MS as identified by Webster, it would have been prima facie obvious to use FGF-9 for the treatment of MS.

Applicant asserts that Webster and Nakamura et al. are speculative, and therefore, the combination is merely an invitation to try. However, the instant specification provides no more than the combination of Webster and Nakamura et al. The instant specification does not administer FGF-9 for the treatment of MS. The instant specification bases the claimed invention on the ability of FGF-9 to stimulate PC 12 cells, which are cells obtained from rat adrenal gland. Therefore, based on the biological activity of FGF-9 on "cells of neuronal origin", Applicant asserts that FGF-9 would be useful for treatment of MS. This is exactly what is taught in the prior art, so it is not clear how the prior art is not enabled but the instant application is enabled. The art teaches the mechanism of MS and what biological activities should be stimulated for treatment, suggests that growth factors would be beneficial and provides a growth factor which has the biological activities indicates as being necessary for treatment of MS. The instant specification provides no more than what is provided in the prior art, and therefore, there is insufficient evidence to suggest that the prior art is not enabling and conclude that the specification is enabling. If the prior art is not enabling, then neither is the instant specification.

Applicant again points to page 114 of Webster as pointing away from the claimed invention. However, as stated previously, the entire disclosure of Webster must be considered and single statements should not be taken out of context. Webster clearly points out the limitations of the experimental models being used to assess the activities of growth factors in vivo and in vitro as well as on cells of human origin versus rodent origin. But the general teaching of Webster is the process of MS and what cells are involved and which biological activities of growth factors would be necessary and desired for use in treatment of MS (see Figure 1). Therefore, it is concluded that Webster does not teach away from using growth factors for the treatment of MS, but does provide useful guidance in selecting a useful growth factor for treatment of MS.

Applicant asserts that the teaching of Webster and Nakamura et al. are conflicting and inconsistent as to the activity of FGF-9 in rodents. This assertion is not based on any facts of record. Webster does not disclose the biological activity of FGF-9, and therefore, cannot provide conflicting data with Nakamura et al.

The rejection of the instant claims is maintained for the reasons of record.

CHRISTINE J. SAUD
PRIMARY EXAMINER

Christine J. Saud